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PATENT NO EP(UK)0231904.....

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**TRANSLATION OF EUROPEAN PATENT (UK)
UNDER SECTION 77(6) (a)**

Date of Publication of the Translation10.7.91.....

The invention concerns a fat mixture with a high content of unsaturated polyethenoid fatty acids and cholesterol with a ratio of docosahexaenoic to arachidonic acid of 1:2.0 to 1:3.0, which has not hitherto been available for human consumption. It further concerns a method for the production thereof as well as the use thereof in the preparation of an infant feed.

Conventional infant feeds contain not more than 0.1 wt.% arachidonic acid and 0.05 wt.% docosahexaenoic acid, as well as not more than 10 mg cholesterol per 100 ml. As it is known that the growing organism needs large quantities of these substances (cholesterol, arachidonic acid, docosahexaenoic acid) in a certain ratio to each other for the synthesis of new cell wall material, particularly during development of the brain, it is questioned whether conventional infant milk feeds are optimal in every case.

Highly unsaturated polyethenoid fatty acids are synthesised in the human organism by chain extension and desaturation from the essential fatty acids linoleic and linolenic acids. This natural synthesis of the highly unsaturated polyethenoid fatty acids is, however, still greatly restricted in the fast-growing infant organism. The newborn baby, particularly the premature baby, is therefore dependent on the exogenous supply of highly unsaturated polyethenoid fatty acids such as e.g. arachidonic and docosahexaenoic acids. In the infant, an inadequate supply of highly unsaturated polyethenoid fatty acids results in other available fatty acids such as e.g. oleic and linoleic acids being incorporated into the lipids of the cell membranes. This may cause changes in the properties of the cell membrane, which may lead to reduced membrane stability, fluidity and altered activity of membrane-bound enzymes.

Apart from the presence of highly unsaturated polyethenoid fatty acids, the cholesterol content of the infant feed is also of importance to the infant's development. Cholesterol is a constituent of the cell membranes and hence, like highly unsaturated polyethenoid fatty acids, of importance to the physicochemical properties thereof. Due to rapid cell growth

in the neonatal stage, increased requirements of cholesterol are assumed during this period. Exogenously supplied cholesterol is also of importance to the development of lipid metabolism.

It is the object of the invention to provide a fat mixture which, by contrast with ordinary fat mixtures used for infant milk feeds, contains larger quantities of the physiologically important, highly unsaturated polyethenoid fatty acids and cholesterol. In connection with this object, using this fat mixture it was possible to produce an infant feed which, by contrast with conventional formula feeds, contains larger quantities of the above-mentioned fatty acids and cholesterol.

Surprisingly, it was found that when a formula feed with the fatty acid contents and ratios claimed in the present application is used, a lipid and fatty acid pattern forms in the infants' blood, which corresponds to that of breast-fed children. Feeding on a conventional formula feed, on the other hand, shows significant differences which suggest a deficiency of long-chain highly unsaturated fatty acids.

The state of the art according to European patent application 0 140 805 provides for supplementation of a formula feed with nucleosides in order to achieve a lipid range in the infants' blood corresponding to breast feeding. By contrast with the findings there, the applicant found that, surprisingly, supplementation with nucleosides is not necessary, because just adding arachidonic and docosahexaenoic acids to a formula feed in the ratios claimed leads to the effects mentioned.

The invention concerns a fat mixture for infant feeds which is characterised by the fact that it contains the highly unsaturated fatty acids arachidonic and docosahexaenoic acids from fats of animal or vegetable origin in a ratio of docosahexaenoic to arachidonic acid of 1:2.0 to 1:3.0, wherein the content of arachidonic acid in the fat mixture is 0.12 to 1.0 wt.% and that of docosahexaenoic acid 0.05 to 0.5 wt.%, with a total content of both acids of 0.17 to 1.5 wt.%.

The fat mixture according to the invention preferably has a

content of arachidonic acid of 0.12 to 1.0 wt.% and of docosahexaenoic acid of 0.05 to 0.5 wt.%, wherein the total content of both acids is within the range of 0.17 to 1.5 wt.%. Furthermore, the fat mixture according to the invention contains cholesterol from fats of animal or vegetable origin preferably in a quantity of 3 to 20 mg/g fat.

The fat mixture according to the invention, containing the above-mentioned unsaturated fatty acids and cholesterol, is obtained by computer-optimised mixing of animal and vegetable fats, wherein fats of dicotyledonous and monocotyledonous plants which have sufficient oleic, linoleic and linolenic acids are used mainly as the base. The simultaneous use of milk fat allows a limited increase in cholesterol. The introduction of arachidonic acid and docosahexaenoic acid is successful only due to the use of fats from algae (*Laminaria*, *Fucus*, *Phaeophyta*, *Rhodophyta* species), fish oils, in particular herring, cod, shark, mackerel, Norway haddock oils and fish liver oils. An important source of the said fatty acids, particularly for cholesterol too, is furthermore organ fats from cattle and pigs. Furthermore, highly refined and deodorised egg oils and egg lecithin fractions are suitable.

The fat mixture according to the invention can thus be obtained by using the following fats:

- fish oils from cod, shark, herring, mackerel, Norway haddock and corresponding fish liver oils,
- egg oil, egg lecithin,
- cows' liver and kidney fat, pigs' liver and kidney fat, cows' brain fat, pigs' brain fat,
- vegetable oils (palm oil, soya oil, cottonseed oil, coconut oil, corn oil, sunflower oil, palm kernel oil,
- oleo oil (beef fat fraction)
- alga oils (*Laminaria*, *Fucus*, *Phaeophyta*, *Rhodophyta*).

A precondition of production of the fat mixtures is that first a detailed analysis is made of the fatty acids, the cholesterol and the phospholipids in the said raw fats. The analyses of lipids can be performed by capillary gas

chromatography and/or high-pressure liquid chromatography. From the corresponding analytical data can then be calculated, using a suitable computer programme, an optimum mixture of the raw fats with the characteristic factors mentioned under claims 1 and 2.

According to an advantageous embodiment, the fat mixture according to the invention is stabilised with alpha-tocopherol. Tocopherol is in this case preferably present in a quantity of 150 to 300 ppm referred to the fat mixture.

Furthermore it is advantageous to use ascorbyl palmitate for stabilisation, which can be used on its own or in addition to alpha-tocopherol, wherein the quantity used is preferably within the range of 150 to 300 ppm referred to the fat mixture.

In production of the fat mixture according to the invention following the example of a fat mixture below, the fats and oils to be used are heated, mixed and then reacted with 250 ppm each of ascorbyl palmitate and alpha-tocopherol for stabilisation.

Example of fat mixture

2.0% liver fat (cow, pig)
5.5% egg oil/egg lecithin
1.0% fish oil (deodorised, devitaminised)
28.0% oleo oil
4.5% corn oil
6.0% soya oil
38.0% palm oil, liquid
15.0% coconut/palm kernel oil

Fatty acid composition (in wt.%)

lauric acid	c12	6.46
myristic acid	c14	3.78
palmitic acid	c16	25.6
stearic acid	c18	8.42
oleic acid	c18:1w9	35.5
linoleic acid	c18:2w6	12.7
linolenic acid	c18:3w3	0.91

arachidonic acid	c20:4w6	0.39
docosahexaenoic acid	c22:6w3	0.15
P/S ratio		0.32
c22:6w3/c20:4w6 ratio		1:2.5
cholesterol (mg/g fat)		4.2
(= 15 mg cholesterol in 100 ml liquid feed)		

The fat mixture according to the invention is suitable for the preparation of an infant and premature baby feed. The invention thus also concerns the use of the fat mixture according to the invention for the preparation of an infant feed.

The vegetable or animal protein-based infant feed to be prepared with this fat mixture is in the form of an instantly soluble powder or a liquid milk. The liquid product is sterilised in the usual way or sterilised at ultrahigh temperature (UHT) and packaged aseptically.

The substances which are used here may be, for example, the following:

- a) demineralised whey powder
- b) lactose
- c) skim milk, liquid (8.5%)
- d) mineral salts
- e) vitamins
- f) fat mixture according to the invention.

The tables below show the typical composition of a liquid infant feed which was prepared using the fat mixture from the example.

Table I

water content	87.4%
proteins	1.5%
lipids	3.6%
carbohydrates	7.2%
mineral salts	0.26%

calorific value	285 kJ/100 ml
cholesterol	15 mg/100 ml

Table II fatty acid composition (in wt.%)

lauric acid	c12	6.46
myristic acid	c14	3.78
palmitic acid	c16	25.60
stearic acid	c18	8.42
oleic acid	c18:1w9	35.50
linoleic acid	c18:2w6	12.70
linolenic acid	c18:3w3	0.91
arachidonic acid	c20:4w6	0.39
docosaheptaenoic acid	c22:6w3	0.15

Table III content of mineral salts (mg/100 ml)

sodium	25
potassium	50
calcium	60
magnesium	6
phosphorus	40
chloride	20

Table IV vitamins (/100 ml)

vitamin A	201 I.U.
vitamin B ₁	0.04 mg
vitamin B ₂	0.05 mg
vitamin B ₆	0.03 mg
vitamin B ₁₂	0.15 µg
vitamin C	5.97 mg
vitamin D ₃	40.2 I.U.
vitamin E	0.61 mg
biotin	1.12 µg
Ca-D pantothenate	0.40 mg
folic acid	10.13 mg
niacinamide	0.40 mg

The composition of the standard solution (13 g powder/90 ml water) of the powdered product is the same as that of the liquid product.

Comparison of the fatty acid composition (in wt.%) and cholesterol content (in mg/100 ml) of conventional and new formula feeds

	conventional	new
c12	5.2	4.7
c14	3.8	3.7
c16	28.1	28.5
c18	8.4	9.2
c18:1w9	33.2	36.5
c18:2w6	12.6	11.7
c18:3w3	0.77	0.63
c20:3w6	ND	0.04
c20:4w6	ND	0.23
c22:5w3	ND	0.05
c22:6w3	ND	0.08
P/S ratio	0.29	0.28
c22:6w3/c20:4w6 ratio	-	0.35
cholesterol	4.0	18.0

ND = not detectable

Claims

1. Fat mixture for infant feeds, characterised in that it contains the highly unsaturated fatty acids arachidonic and docosahexaenoic acids from fats of animal or vegetable origin in a ratio of docosahexaenoic to arachidonic acid of 1:2.0 to 1:3.0, wherein the content of arachidonic acid in the fat mixture is 0.12 to 1.0 wt.% and that of docosahexaenoic acid 0.05 to 0.5 wt.%, with a total content of both acids of 0.17 to 1.5 wt.%.
2. Fat mixture according to claim 1, characterised in that the content of cholesterol from fats of animal or vegetable origin is 3 to 20 mg/g fat.
3. Fat mixture according to claims 1 and 2, characterised in that in addition it contains alpha-tocopherol in a quantity of 150 to 300 ppm.
4. Fat mixture according to any of claims 1 to 3, characterised in that in addition it contains ascorbyl palmitate in a quantity of 150 to 300 ppm.
5. Method for the preparation of the fat mixture according to claim 1, characterised in that fish oils, egg oil, egg lecithin, fat fractions of cows' and pigs' brains and organ fat (kidney, liver) of cows or pigs, plant oils of dicotyledonous and monocotyledonous plants, oleo oil and/or alga oils are used for the preparation thereof and in the process the ratio of the respective oils and fats is adjusted in such a way that the ratio of docosahexaenoic to arachidonic acid is 1:2.0 to 1:3.0.
6. Use of the fat mixture according to claims 1 to 4 for the preparation of an infant and premature baby feed.

Patent claims for the member states: GR and ES

1. Method for the preparation of a fat mixture for infant feeds which contains the highly unsaturated fatty acids arachidonic or docosahexaenoic acid from fats of animal and vegetable origin in a ratio of docosahexaenoic to arachidonic acid of 1:2.0 to 1:3.0, wherein the content of arachidonic acid in the fat mixture is 0.12 to 1.0 wt.% and that of docosahexaenoic acid 0.05 to 0.5 wt.%, with a total content of both acids of 0.17 to 1.5 wt.%, characterised in that fish oils, egg oil, egg lecithin, fat fractions of cows' and pigs' brains and organ fat (kidney, liver) of cows or pigs, plant oils of dicotyledonous and monocotyledonous plants, oleo oil and/or alga oils are used for the preparation thereof and in the process the ratio of the respective oils and fats is adjusted in such a way that the ratio of docosahexaenoic to arachidonic acid is 1:2.0 to 1:3.0.
2. Method according to claim 1, characterised in that the content of cholesterol from fats of animal or vegetable origin is 3 to 20 mg/g fat.
3. Method according to claims 1 and 2, characterised in that in addition alpha-tocopherol is added in a quantity of 150 to 300 ppm.
4. Method according to any of claims 1 to 3, characterised in that in addition ascorbyl palmitate is added in a quantity of 150 to 300 ppm.
5. Use of the fat mixture according to claims 1 to 4 for the preparation of an infant and premature baby feed.